



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0728; FRL-9155-01-OCSPP]

Agency Information Collection Activities; Proposed Renewal and Request for Comment; Consolidation of Certain Reporting and Recordkeeping under Section 8 of the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit a request to renew and consolidate existing approved Information Collection Requests (ICRs) to the Office of Management and Budget (OMB). Before submitting the consolidated ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The consolidated ICR is entitled: “Reporting and Recordkeeping Under Section 8 of the Toxic Substances Control Act (TSCA)” and is identified under EPA ICR No. 2703.01 and OMB Control No. 2070-[NEW]. EPA is consolidating several ICRs covering reporting and recordkeeping activities under TSCA Section 8 to streamline the presentation of the paperwork burden estimates for these various activities and eliminate any duplication, which will in turn is expected to reduce the administrative burden for both the public reviewers and the Agency. The ICR and accompanying materials are available in the docket for public review and comment.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0728, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Mission Support Division (7101M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1204; email address: sleasman.katherine@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting

electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Information Collection Activity or ICR Does this Action Apply to?

Title: Recordkeeping and Reporting Under Section 8 of the Toxic Substances Control Act (TSCA)

ICR numbers: EPA ICR No. 2703.01; OMB Control No. 2070-[NEW].

ICR status: This ICR reflects the consolidation of the following currently approved ICRs:

1. “Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies” (EPA ICR No. 0575.16, OMB Control No. 2070-0004), which is currently approved through November 30, 2022;

2. “Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment” (EPA ICR No. 1031.12, OMB Control No. 2070-0017), currently approved and pending renewal (86 FR 58905, October 25, 2021) (FRL-9137-01-OMS);

3. “TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR)” (EPA ICR No. 0586.14, OMB Control No. 2070-0054), which is currently approved through December 31, 2022; and

3. “Chemical-Specific Rules, TSCA Section 8(a)” (EPA ICR No. 1198.10, OMB Control No. 2070-0067), which expired June 30, 2018, and is pending reinstatement.

Under the PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the ***Federal Register*** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: These ICRs all involve reporting and recordkeeping activities established under TSCA section 8 for specific chemical substances. Although imposed for a specific chemical substance, the activities are already established and only vary based on the specific authority under TSCA section 8 and the need for the information for that chemical. EPA is consolidating these ICRs to streamline the presentation of the paperwork burden estimates for these various activities, which will in turn facilitate and reduce the administrative burden for both the public reviewers and the Agency in terms of reviewing and updating the ICR every three years as required by the PRA, as well as to allow for a better assessment of the paperwork burden and costs associated with reporting and recordkeeping activities established under TSCA section 8 for specific chemical substances.

This ICR covers reporting and recordkeeping requirements imposed under the authorities in TSCA section 8, for persons who manufacture (the term “manufacture” includes import under TSCA) or process chemical substances, mixtures, or categories, or distribute them in commerce. The purpose of the information collection activities is to collect data that will help the Agency evaluate the potential for human health and environmental risks that may be caused by the manufacture, processing, and distribution in commerce of chemical substances, mixtures, or categories.

The TSCA section 8(a) Preliminary Assessment Information Rule (PAIR) requires manufacturers and importers of certain chemical substances to submit information about production, use, and/or exposure-related data. Under TSCA section 8(a), persons who manufacture, import, or process certain chemical substances or mixtures, or propose to manufacture, import, or process certain chemical substances or mixtures, are subject to chemical-specific rules promulgated under TSCA section 8(a). A chemical-specific “8(a) rule” requires more detailed and more types of information than is required by a PAIR rule. For example, a chemical-specific “8(a) rule” might require information that includes, but is not limited to, chemical names, categories of use, production volume, byproducts of chemical production,

existing data on health and environmental effects, exposure data, and disposal information.

Under TSCA section 8(c), persons who manufacture, import, process, or distribute in commerce any chemical substance or mixture must keep records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. TSCA section 8(c) requires that allegations of adverse reactions to the health of employees be kept for thirty years, and all other allegations be kept for five years. The rule also prescribes the conditions under which a firm must submit or make the records available to a duly designated representative of the Administrator.

Finally, under TSCA section 8(d), persons, who manufacture, import, process, or distribute in commerce (or propose to manufacture, import, process, or distribute in commerce) certain chemical substances and mixtures, are required to submit to EPA lists and copies of health and safety studies in their possession which relate health and/or environmental effects of the chemical substances and mixtures. The 8(d) rules are codified in 40 CFR part 716. To comply, respondents must search their records to identify any health and safety studies in their possession, make copies of relevant studies, list studies that are currently in progress, and submit this information to EPA.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average one hour per response. The consolidated ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

Respondents/Affected entities: Entities potentially affected by this ICR are manufacturers (including imports) or processors of chemical substances of mixtures, which are mostly chemical companies classified under the North American Industrial Classification System (NAICS) Codes 325 and 324.

Estimated total number of potential respondents: 13,294.

Frequency of response: On occasion.

Estimated average number of potential responses: 26,425.

Estimated total annual burden hours: 26,226 hours.

Estimated total annual costs: \$ 5,109,515, which includes an estimated burden cost of \$ 0 for non-burden hour paperwork costs, e.g., capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approvals?

This ICR will be submitted as a new ICR, which means that the total estimates for burden and costs provided in Unit IV. will be considered increases. However, since this ICR represents the consolidation and reinstatement of previously approved ICRs, the Agency compared the total estimates in this ICR to the estimated burden and costs previously approved. This identified an overall increase in the estimated total burden of 78 hours (26,226 – 26,148) and a corresponding increase in the estimated total burden cost of \$ 297,119 [\$5,109,515 – \$4,812,396]. This overall increase is due to the consolidation and reinstatement of the individual ICRs, and adjustments in EPA’s estimates of the number of respondents, the activity burden, and updates to the wage rates and material costs to reflect 2021 dollars. These changes are adjustments.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the consolidated ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another ***Federal Register*** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity for the public to submit additional comments for OMB consideration. Once this ICR is approved by OMB, it will replace the existing ICRs.

If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: March 2, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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